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JUN 05 2006

U.S. Application No. 09/822,261

Attorney Docket No.: 8123.002CON

**d.) Remarks.**

Applicant has amended claims 1 and 65 as suggested by the Examiner. No new matter or new issues are presented with these amendments. Accordingly, claim 1-29, 46-75 are currently pending.

**Remarks Regarding 35 U.S.C. § 112, Second Paragraph**

Claims 1-19 and 60-75 stand rejected, under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Applicant respectfully traverses this rejection.

It is alleged that the phrases "capable of being" render these claims indefinite. As suggested by the Examiner, this phrase has been deleted from these claims. Thus, this rejection is moot.

**Remarks Regarding 35 U.S.C. § 103(a)**

A. Claims 1-11, 18-26, 29, 46, 47 and 51-75 stand rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Snowden (U.S. Patent Application No. 2002/0026332 A1), in view of Shepard (U.S. Patent No. 6,026,363).

B. Claim 12 stands rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Snowden in view of Shepard, and further in view of Baker (PCASSO).

C. Claims 13-15, 27, 28 and 48-50 stand rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Snowden in view of Shepard, and further in view of Malik (U.S. Application No. 2001/0037219 A1).

D. Claims 16 and 17 stand rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Snowden in view of Shepard, and further in view of Shear (U.S. Patent No. 4,827,508).

According to the Office Action, all rejections under 35 U.S.C. § 103(a) are maintained for the same reasons set forth in the previous Office Action. Applicant respectfully traverses all these rejections and all comments made by the Examiner in the

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Office Action. Further, Applicant herein incorporates all remarks made in Applicant's prior Amendments and responses to the PTO.

The Examiner kindly provided comments in the Office Action directed to Applicant's prior Amendment. Applicant addresses each of those comments below.

I. Applicant's Affidavit is Sufficient to Overcome both Snowden and Malik

(i) The Examiner has Misunderstood MPEP 715.02

In the Office Action, the Examiner alleges that the statements in the Affidavit by Dr. Knaus and Mr. Marks are insufficient because they "fail to establish either conception of and/or reduction to practice of the whole invention claimed or something falling within the claims," and "because "there is no clear nexus between the materials and the claimed subject matter" (Office Action, paragraph 11; emphasis in original). Applicant respectfully disagrees.

Pursuant to the Manual of Patent Examining Procedure § 715.02 ("MPEP" 715.02), Applicant only needs to show that the Affidavit contains the elements of the claimed invention found in the prior art:

*[A]n affidavit is not insufficient merely because it does not show the identical disclosure of the reference(s) or the identical subject matter involved in the activity relied upon. If the affidavit contains facts showing a completion of the invention commensurate with the extent of the invention as claimed is shown in the reference or activity, the affidavit or declaration is sufficient....(Emphasis added.)*

Applicant provided a thorough comparison between the elements of the claims and the relevant portions of each of the cited references. As previously shown by Applicant, the Affidavit contains facts showing a completion of the invention commensurate with the extent of the invention as claimed by the Examiner to be shown in the reference that was provided. Pursuant to MPEP 715.02, this is precisely what has been demonstrated by Applicant. For the Examiner to require Applicant to demonstrate "more" than that which is shown by the reference is error.

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(ii) The Examiner has Misunderstood the Nexus Requirement

In the Office Action, and also during the Interview of October 20, 2005, the Examiner stated that Applicant's Affidavit fails because there is no "nexus" between the Affidavit and the instant claims (final Office Action, page 15). This is clear error. A requirement for a "nexus" between an Affidavit and a claimed invention is found only under 37 C.F.R. § 1.132, not 37 C.F.R. § 1.131.

II. The Cited Combinations Do Not Suggest the Claimed Invention

Applicant respectfully traverses these rejections and incorporates all remarks set forth in all of applicant's prior Responses. Applicant also respectfully traverses all of the Examiner's comments in the Office Action including all of the Examiner's conclusions with respect to the cited references. None of the references in the Office Action discloses or suggests, either alone or in combination, applicant's claimed invention.

(i) The Claim Element of "Nonrepudiation"

Nonrepudiation is positively recited as an element of Applicant's claimed invention (e.g., claims 1, 8, 9, 10, 26, 46, 63, 65, 70 and 71). As recited in claim 1, medical information contained within medical records is verified as accurate and correct such that: "*one or more records of the collection possess a characteristic of nonrepudiation.*" This element is also clear from the specification: "*Medical records that are verified as accurate attain the aspect of nonrepudiation (i.e. that the accuracy and correctness of the information [in the medical record] is as good or better than exists at the source from which the records were obtained) and may for all purposes be relied upon*" (specification, page 17, lines 14-17). Applicant respectfully asserts that this claim element is understood by those of ordinary skill in the art. Applicant is not incorporating a definition from the specification, but merely demonstrating that the specification is consistent with the context and the plain meaning of this term in the claims.

(ii) The Claim Element of "Certification"

Certification is positively recited as an element of Applicant's claimed invention. (e.g., claims 1, 21, 22, 23, 63, 64 and 72). As recited in claim 1, the invention comprises a collection of medical records wherein "*medical information contained within said medical*

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records is verified as to accuracy and certified for accuracy." As stated by Applicant: "The invention may include a form of medical record that can be completed at one of a plurality of certification levels" (specification, page 15, lines 12-13). "Certification levels refer to standards of verification such as, for example, 'initial' being self-certification wherein the member certifies that the record is correct, 'basic' whereby the system provider certifies that the record is complete for all information gathered ...." (specification, page 15, lines 22-25; and claims 20, 37, 43). Applicant respectfully asserts that this claim element is understood by those of ordinary skill in the art. Applicant is not incorporating a definition from the specification, but merely demonstrating that the specification is consistent with the context and plain meaning of this term in the claims.

### **III. Response to Examiner's Comments**

In the instant Office Action, the Examiner kindly provided comments directed to Applicant's prior Amendment. Applicant respectfully responds to each of those comments as follows:

- (i) The Examiner rebuts Applicant's statement that "data integrity," as disclosed in Snowden does not imply the characteristic of nonrepudiation, by asserting that "Applicant merely pointed to a passage in the specification that broadly defines non-repudiation as 'provides a level of assurance to the correctness and accuracy of records,' and also by asserting that nonrepudiation is disclosed in Shepard at column 13, line 54, to column 14, line 9.

Applicant respectfully disagrees. First, Snowden's data integrity is neither the same as nor similar to the claim aspect of nonrepudiation. Snowden's reference to data integrity is in the following context: "Key factors in the overall system design are the issues of data ownership, data integrity, data access, confidentiality and allowed uses of the data." None of this has anything to do with nonrepudiation or even assurance as to accuracy or correctness of the medical information contained within medical records.

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Second, Applicant has reviewed the cited passages of Shepard and can find no reference to the claim aspect of nonrepudiation. The cited passage of Shepard refers to simple reviewing of medical records as it takes place conventionally in a hospital. Clearly the Examiner does not understand what nonrepudiation means. Applicant respectfully requests that the Examiner review the instant specification to understand the concept on nonrepudiation. Applicant believes that, upon a more careful review, it will be clear that neither Snowden nor Shepard discloses nonrepudiation or anything suggestive of nonrepudiation.

Applicant does not equate nonrepudiation with accuracy, either in the instant claims or specification, or in any responsive arguments, and there is no basis for the Examiner's doing so here.

- (ii) The Examiner rebuts Applicant's argument that neither Snowden nor Malik is prior art by asserting that Applicant's Affidavit is insufficient.

As more fully discussed above, Applicant respectfully asserts that the Affidavit is sufficient in all respects to swear behind both Shepard and Malik.

- (iii) The Examiner rebuts Applicant's arguments that Shepard teaches away from Applicant's claimed invention because Shepard is a hospital-based system, whereas Applicant's claimed system is patient-based, by asserting that "the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of a primary reference; nor is it that the claimed invention must be expressly suggested in any one reference. Rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art."

Applicant respectfully disagrees with the Examiner's analysis. A hospital-based system and a patient-based system are not only conterminous, they are incongruous. A hospital-based medical information system and a patient-based system are independent,

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separate and unique entities. The goals, content, and management of each system are distinct.

Applicant respectfully requests that the Examiner review Applicant's specification to understand these important features. Applicant asserts that one cannot incorporate a hospital-based medical information management system into the claimed patient-based, medical information management system. Accordingly, Applicant respectfully requests that the Examiner review Applicant's specification to understand these important features.

- (iv) The Examiner rebuts Applicant's arguments that there is no suggestion or motivation for combining the references as asserted by the Examiner, by asserting that the proposed combinations are "logical to one skilled in the art."

Applicant respectfully asserts that motivation is not an optional requirement for obviousness. To establish *prima facie* obviousness, the Examiner must show in the prior art some suggestion or motivation to make the claimed invention, a reasonable expectation for success in doing so, and a teaching or suggestion of each claim element (See, e.g., *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ 2d 1941 (Fed. Cir. 1992); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986); *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)). Mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole (*Id.* at 1355, 1357). Rather, to establish a *prima facie* case of obviousness based on a combination of elements disclosed in the prior art, the Examiner must articulate the basis on which it concludes that it would have been obvious to make the claimed invention (*Id.*). In practice, this requires that the Examiner "explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious" (*Id.* at 1357-59). This entails consideration of both the "scope and content of the prior art"

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and "level of ordinary skill in the pertinent art" aspects of the *Graham* test. As the Federal Court asserted:

*"It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art." Bausch & Lomb, Inc., v. Barnes-Hind/Hydrocurve, Inc., 796, F.2d 443, 448 (Fed. Cir. 1986) (quoting In re Wesslau, 355 F. 2d 238, 241 (CCPA 1965).*

The Examiner failed to establish a prima facie case for obviousness under her own analysis. This is highlighted by the Examiner's statement in the Office Action that it would be "logical to one skilled in the art." This is non-responsive. Absent both a suggestion of each and every aspect of the claimed invention and the necessary motivation, the rejection under 103(a) cannot stand.

In summary, at least Snowden and Malik cannot be considered prior art, and none of the cited references suggests Applicant's claimed invention. In addition, the Examiner admits that none of the references provide the required motivation to one skilled in the art that would lead to the instant claims. Accordingly, all obviousness rejections set forth in the Office Action are both moot and overcome. Applicant respectfully requests that these rejections be withdrawn and that the application be deemed allowed.

**Remarks Regarding the Examiner's Failure to Review Claim 20**

Applicant respectfully notes that the Examiner has provided no comments directed to at least one of Applicant's claims. No comments were made in the most recent final Office Action, and no comments were made in any previous Office Actions, with respect to one important aspect of claim 20.

Claim 20 recites, in part, that: *"wherein the medical information of at least one medical record of the plurality has been vetted, such that the medical information of said at least one medical record is better than exists at a source site from which the medical record was obtained."* None of the cited references, nor any comments by the Examiner, discloses or

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suggests a computer-networked system wherein the medical records are *more* accurate than the records collected from the source sites from which the records were originally obtained.

Further, there are no comments in the final Office Action, or any previous Office Actions which express or even imply that medical information in a medical record could be better than exists at the source from which the record was obtained. This claim, at least, should be immediately declared to be allowable as never having been subject to any rejections. In the absence of an allowance, Applicant is entitled to a full and proper explanation as to the Examiner's reasoning for any rejection.

If an Advisory Action is forthcoming, Applicant respectfully requests that the finality of this Office Action be withdrawn and that Applicant be provided with a full, fair and thorough basis on which to argue Applicant's appeal.

#### Conclusion

The application including pending claims 1-29 and 46-75, are believed to be in condition for allowance and the prompt issuance of a Notice of Allowance is respectfully requested.

If the Examiner believes that another interview, either in person or by telephone, would advance the prosecution of this application, such an interview would be welcomed, and the Examiner is encouraged to contact the undersigned.



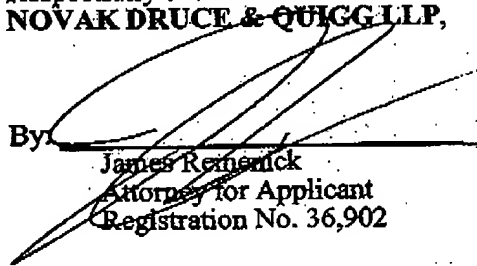
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No fees are believed to be due with the filing of this Amendment. However, if any fees are later determined to be due, including any fees for an extension of time, applicant respectfully requests that extension and that all such fees be charged to Deposit Account No. 14-1437, referencing Attorney Docket No. 8123-002CON.

Respectfully submitted  
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Date: June 5, 2006

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